REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Entry after final of the above amendments is respectfully requested at least because the above amendments resolve issues associated with the 35 U.S.C. § 112 rejections. The amendments place the application in better form for Appeal by materially reducing or simplifying the issues for Appeal. No new matter is added.

Claims 1-23 are pending in this application.

Rejections under 35 U.S.C. § 112

Claims 1-23 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although Applicants do not necessarily agree with the Examiners' rejection, Applicants have amended claims 1, 7, 9, 17 and 19 taking into consideration the Examiners Comments. Applicants have amended these claims in order to place the application in better form for Appeal by materially reducing or simplifying the issues for Appeal.

The Examiner has rejected several claims because of a lack of clarity. However, the Examiner has indicated that at least one interpretation is reasonable for each of these claims. Therefore, Applicants submit each of these claims are clear by the standards of 35 U.S.C. § 112, second paragraph.

Applicants further submit that one interpretation renders the claims clear. However, the claims are not limited as such but instead as one skilled in the art would interpret the claims in light of the specification.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1-23 under 35 U.S.C. § 112, second paragraph.

Example Embodiments of the Present Application

Independent claim 1 recites a method for carrying out a clinical study involving a patient comprising "reading by a computer associated with a non-study doctor assigned to the patient at least one of the study-related data and the patient-related data." Example non-limiting embodiments of this feature are discussed, for example, in paragraphs [0004]-[0010] and FIG. 1 of the subject specification.

A special study doctor is assigned to a patient who is extremely well informed about very strict and narrow marginal conditions with respect to the study. For example, the patient cannot be given certain medications if he/she continues to participate in the study.

A doctor who is not familiar with the study, for example the claimed non-study doctor assigned to the patient, does not know these restrictions and particular features of the clinical study relating to the patient. The example embodiments, however, deals precisely with this problem and solves this problem.

These problems do not occur with "normal medical actions" – e.g. as described in Brimm under "normal actions" in a hospital information system.

Example embodiments provide the particular study-related data, which clearly differ from normal patient data, in a suitable manner to a doctor who is not familiar with the study. The problem is solved according to example embodiments by providing a memory and/or an access authorization to the storage network which can be carried along by the patient.

As is illustrated in paragraphs [0052]-[0056] of the present application, serious health complications due to giving the patient 4 a drug are prevented by granting a non-study doctor access to memory 12. The non-study doctor 22 connects the memory 12 to their laptop 25. As indicated by arrows 27, the family doctor 22 reads the study data 14 and patient data 16 out from the memory 12 in an information step 26 and is a thereby informed of the clinical study 2 being carried out on the patient 4. From the study information 14, however, the non-study doctor determines that a drug is not compatible with the active agent of the clinical study. Therefore, the non-study doctor chooses a different drug that is compatible.

Rejections under 35 U.S.C. § 103

Claims 1-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,072,383 to Brimm et al. ("Brimm") in view of US Patent No. 6,168,563 to Brown ("Brown"). Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner acknowledges that Brimm does not expressly disclose a clinical study. However, the Examiner states "Brimm discloses a medical regimen, ..., and a clinical study is a medical regimen." The Examiner further asserts that the term "clinical study" is a nonfunctional term. Applicants respectfully disagree.

Brimm is directed to a hospital information system having data processing system including terminals for display and data entry. (See Abstract). In the system, patient data is entered via the terminals, organized hierarchically, and displayed to individuals with proper access. (See *Id.*). Further, the hospital information system of Brimm also provides for a time-oriented task list generated from data which had been entered from physicians and nursing orders. (See *Id.*).

However, Brimm is silent with regard to, and therefore does not even include, clinical studies. Further, Brimm is also does not include interfacing with physicians that have no connection to a particular clinical study or a non-study doctor.

Moreover, the hospital information system of Brimm relates to the hospital's internal processes. (See Abstract and column 3: lines 58-68 and column 4: lines 1-49) For instance, all the data associated with one patient is available within the hospital information system. Accordingly, Brimm only stores internal process information. Therefore, Brimm is does not contemplate, and therefore does not disclose, storing any data/information associated with a clinical study.

Accordingly, Brimm does not teach or fairly suggest "[a] method for carrying out a **clinical study** involving a patient," and "storing on a memory, study-related data associated with a protocol of the **clinical study**," and "storing, on the memory, patient-related data associated with the patient and **the clinical study**," as required by claim 1.

Brown does not disclose the aforementioned limitations and the Examiner does not rely on Brown to disclose the aforementioned limitations.

For at least the reasons described above, Brimm and Brown, alone and in combination (assuming *arguendo* that Brown could be combined with Brimm, which the Applicants do not admit) do not teach each and every limitation of claims 1, 7 and 17. Because Brimm and Brown do not teach or fairly suggest each and every limitation of independent claim 1, Brimm in view of Brown does not render claim 1 obvious. Claims 7 and 17 are patentable for reasons at least somewhat similar to those discussed above with regard to claim 1, noting that claims 7 and 17 should be interpreted solely based on the limitations set forth therein. Claims 2-6, 8-16 and 18-23 are patentable at least by virtue of their dependency from an independent base claim.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1-23 under 35 U.S.C. § 103(a).

CONCLUSION

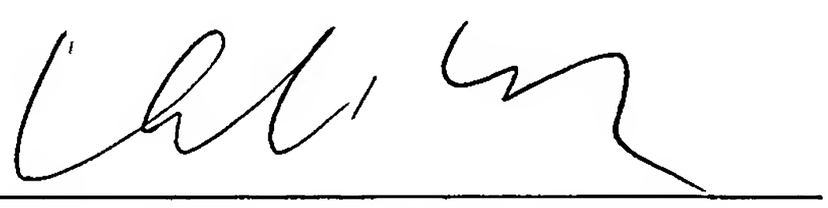
In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By 

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